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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,797	04/17/2001	Henry C. Lin	(18810-81652)	9913

7590 09/30/2004

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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/837,797

**Applicant(s)**

LIN ET AL.

**Examiner**

Rodney P. Swartz, Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 86-123 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 86-112 and 116-123 is/are rejected.
- 7) ☒ Claim(s) 113-115 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 13July2004, is acknowledged. Claims 46-85 have been canceled. New claims 86-123 have been added.
2. Applicants' Terminal Disclaimer, received 13July2004, is acknowledged and has been entered.
3. Claims 86-123 are pending and under consideration.

### **Priority Statement**

4. The priority statement at the beginning of the specification must be updated to recite applicants' priority claim to Pct applications.

### **Rejections Moot/Withdrawn**

5. The provisional rejection of claims 46-85 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of copending Application No. 09/374,142 is moot in light of the cancellation of the claims.
6. The rejection of claims 46-85 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of SIBO in irritable bowel syndrome patients with a predigested nutritional formula VIVONEX® alone, does not reasonably provide enablement for treatment of SIBO or other SIBO caused conditions by deprivation of all/some nutrients or single nutrient nor of combination therapies with enzymes, absorption alterations, or any other therapies, is moot in light of the cancellation of the claims.

### **Rejection Maintained**

7. The rejection of claims 46-85, now replaced by new claims 86-1112 and 116-123, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of SIBO in irritable bowel syndrome patients with a predigested nutritional formula VIVONEX®

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alone, does not reasonably provide enablement for treatment of SIBO or other SIBO caused conditions by deprivation of all/some nutrients or single nutrient nor of combination therapies with enzymes, absorption alterations, or any other therapies, is maintained for reasons put forth in the original rejection of claims 46-85.

Applicants argue that new claims 113-115 are drawn to a method using VIVONEX® and therefore these claims are enabled.

The examiner has considered applicants' argument concerning new claims 113-115 and finds the argument persuasive.

Applicants argue that new claims 86-112 and 116-123 also are enabled because the specification provides considerable guidance for practicing the novel methods claimed without undue experimentation. Applicants argue that the one example using VIVONEX® provides sufficient guidance for determining what forms of nutrient deprivation may be used to treat the recited conditions because VIVONEX® is representative of diets of partially predigested nutrients.

The examiner has considered applicants' arguments, but does not find them persuasive for the reasons put forth in the original rejection. In addition, while the particular formulation of VIVONEX® does appear to enable the claimed methods, the scope of the claims is drawn to any formulation of nutrients or partially predigested nutrients. The specification is insufficient for support of any/all formulations of whole or partially predigested nutrients other than the particular formulation of VIVONEX®.

#### **Claim objections**

8. Claims 113-115 are objected to as being dependent from rejected claims.

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### Conclusion

9. No claims are allowed.
10. Applicants' amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

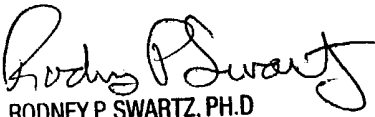
If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

September 28, 2004